

REMARKS

Claims 1, 3-6, 8-13, and 15-22 are pending. Claims 1 and 3-6 have been allowed. Claims 8-13, 16-20, and 22 have been withdrawn by the Examiner. Claims 15 and 21 have been rejected. Claims 15 and 21 are presently amended. In view of the discussion below, Applicants now believe that the application is in condition for allowance.

Claim Rejections 35 U.S.C. § 102

The Examiner has rejected claim 21 under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,340,357 (Poulsen). In particular, the Examiner states that Figure 1 of Poulsen discloses "a syringe comprising a barrel (10) and a plunger (12) comprising a forward and rearward surface and a drive ram coupling extension (3) free of apertures and comprising a plurality of knurls (threading) protruding out rearwardly from the plunger, wherein the knurls are oriented transversely to the longitudinal axis and are adapted to . . . [be] within an area enveloped by a coupling mechanism (13) of an injector drive ram." Applicants respectfully disagree.

As an initial matter, Applicants note that Poulsen has only been cited under 35 U.S.C. § 102(e). Applicants, in this response, argue that Poulsen does not anticipate claim 21 of the present application. However, this is not an acknowledgment or admission that the invention of the present application does not predate Poulsen such that Poulsen would be removed a § 102(e) prior art.

Turning now to the substance of the rejections: Applicants note that the extension of claim 21 is particularly recited as being a "drive ram coupling extension." As can be seen from Figure 1 of Poulsen, the threaded piston rod (3) (which the Examiner considers to be the "drive ram coupling extension") is already coupled to a mechanism to move the plunger within the syringe barrel: a nut (4) and injection button (5). This nut (4) and injection button (5) are pressed to dispense fluid within a syringe, but are not motor driven, and so are not a "drive ram," as found on injectors such as those described in the present application. That the injection button (5) is manually pressed (and thus does not include a drive ram) is clear from the specification of Poulsen. At least column 1, lines 16-20, of Poulsen state that the "invention relates to drug delivery systems ... the delivery being made by pressing a button until it abuts a stop." And at least column 2, lines 18-21, state, "the use of an electric motor in an injection device is known but in such known devices the motor is used to perform the injection. However, it has appeared that it is preferable to make the injection manually" Thus, Applicants submit that Poulsen does not disclose any drive ram, as is found on injectors such as those described in the present application. Since there is no drive ram, Applicants submit that the piston rod (3) cannot be a "drive ram coupling extension" as recited by claim 21.

Applicants had previously made a similar argument in responding to a rejection of independent claim 1 (now allowed) over U.S. Patent No. 3,747,479

(Nightingale) in the January 13, 2005 Office Action. Applicants argued that Nightingale does not disclose a "drive ram engaging coupling element." This element is recited in claim 1, and would inherently require a drive ram in order to render the element a "drive ram engaging coupling element." However, since Nightingale does not disclose a drive ram, it cannot disclose a drive ram engaging coupling element (as supported by the Declaration of Frank M. Fago, dated October 25, 2005, para. 5). The Examiner accepted this argument, and independent claim 1 has subsequently been deemed allowable. The same reasoning holds true for overcoming the present rejection of claim 21.

In view of the above, Applicants respectfully request a withdrawal of the rejection of claim 21 over Poulsen under 35 U.S.C. § 102(e).

Claim Rejections 35 U.S.C. § 103

The Examiner has rejected claim 15 under 35 U.S.C. § 103(a) as being unpatentable over Poulsen as modified by U.S. Patent No. 5,662,612 (Niehoff). The Examiner points to Fig. 1 of Poulsen as disclosing a syringe including a barrel (10) and a plunger (2) having forward and rearward surfaces; and a drive ram coupling extension (3), free of apertures and having a plurality of knurls, protruding out rearwardly from the plunger, wherein the knurls are oriented transversely to the longitudinal axis and are adapted to be within an area enveloped by a coupling mechanism (13) of an injector drive ram.

The Examiner acknowledges that Poulsen does not disclose a plunger having "a forwardly facing surface being of a slope which conforms to the slope of an interior of the conical front wall," as recited in claim 15. However, the Examiner points to Fig. 1A of Niehoff as teaching a plunger having a sloped forwardly facing surface, and suggests that it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the invention of Poulsen with a plunger having a sloped forwardly facing surface as taught by Niehoff. Applicants respectfully disagree.

As stated above, the Examiner acknowledges that Poulsen does not show a plunger having a sloped forwardly facing surface, but points to Niehoff as showing such a plunger, and suggests that it would have been obvious for one skilled in the art to replace the plunger of Poulsen with the plunger of Niehoff. However, in our view, one would not combine the plunger having the sloped front face of Niehoff with the apparatus of Poulsen, because a plunger having such a sloped surface is not needed in Poulsen. Poulsen describes a plunger having a piston rod, and a button that can be screwed on and off threads of the piston rod to alter the distance of a nut from a pin to set a particular amount of a fluid to be injected into a subject. Thus, there is no need to change the shape of the plunger in Poulsen because it already works adequately for its intended purpose. In other words, once the dosage amount has been set, the apparatus and flat-faced plunger of Poulsen accurately deliver that set amount of fluid.

There is no need to alter the shape of the plunger because accurate delivery of fluid is not contingent upon that shape. In fact, if one were to change the shape of the plunger of Poulsen (i.e., to a sloped forwardly facing surface), one would then have to recalibrate the entire injector of Poulsen to ensure that the correct amount of fluid is injected into a subject (because the changed shape would alter the volume of the syringe cavity forward of the plunger). There would be no reason to make this modification.

In view of the above, Applicants request a withdrawal of the rejection of claim 15 over Poulsen in view of Niehoff, under 35 U.S.C. § 103(a).

Claim Objections

The Examiner has objected to claims 15 and 21 because they claim an imaginary longitudinal axis. The Examiner suggests omitting the term "imaginary," and simply claiming a longitudinal axis. In response, claims 15 and 21 have each been amended to remove the recitation of an "imaginary" longitudinal axis.

Conclusion

For the foregoing reasons, it is submitted that all claims are patentable and a Notice of Allowance is respectfully requested.

No fee is believed due with this communication. However, if any fee is deemed due, the Examiner is authorized to charge Deposit Account No. 23-3000.

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The Examiner is invited to contact the undersigned attorney with any questions or remaining issues.

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